Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

comparisone of 5day, 3month, 6month and 1year prognosis of treatment of patient with malignant intracranial hypertension by decompressive craniotomy and hinge cranioplasty in Sina hospital in 2016-2017

Protocol summary

Study aim

comparison of outcome and complication of hinge cranioplsty and decompressive craniectomy in treatment of malignant intracranial hypertension and replacing this method of surgery (hinge cranioplasty) in treatment of malignant intracranial hypertension if outcome is better and complication is less.

Design

Randomized parallel group trial with blinded outcome assessment. randomization was done with sealed envelop method and composed 14 patient underwent hinge cranioplasty and 14 underwent decompressive craniectomy.

Settings and conduct

surgery is done on neurosurgery operation room of Sina hospital with blindness of surgeon about type cranioplasty or craniectomy and ICU care and management by blindness of nurse.

Participants/Inclusion and exclusion criteria

patient who underwent cerebral decompression: 1.patient with diagnosis of ischemic cerebrovascular accident and intracranial hypertension above 20cmHg despite maximum medical therapy or sign of brain herniation or decrease level of consciousnesses or focal neurological deficit. 2.patient with intracerebral hematoma above 30 cc and 5mm midline shift and decrease level of consciousness and focal neurological deficit 3.patient with traumatic subdural hematoma or intracerebral hematoma need operation for hematoma evacuation.

Intervention groups

patient with diagnosis of malignant intracranial hypertension due to internal carotid territory infarction , traumatic and non traumatic intracranial hematoma , subdural hematoma underwent cerebral decompresion with one these two method: decompressive craniotomy or hinge cranioplasty

Main outcome variables

Intracranial pressure Glasgow outcome scale Modified rankin scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180515039678N1**
Registration date: **2018-11-21, 1397/08/30**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-21, 1397/08/30**
Update count: **0**

Registration date

2018-11-21, 1397/08/30

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-15, 1396/10/25

Expected recruitment end date

2020-01-15, 1398/10/25

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
comparisone of 5day, 3month, 6month and 1year prognosis of treatment of patient with malignant intracranial hypertension by decompressive craniotomy and hinge cranioplasty in Sina hospital in 2016-2017

Public title
hinge cranioplasty in treatment of malignant intracranial hypertension
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patient with diagnosis of malignant intracranial hypertension indicate cerebral decompression despite medical management hemorrhagic and ischemic infarct of internal carotid territory patient with diagnosis of unilateral internal carotid territory intracranial hematoma that indicate surgery without coincidence hematoma E.g Subdural hematoma patient with traumatic unilateral temporal, parietal, frontal subdural hematoma or combination of them in one side even with same side contusion(not need evacuation) with intracranial pressure above 20cmHg or protrusion of brain parenchym out of site of craniectomy
Exclusion criteria:
pregnant women patient died during first day after operation occipital or cerebellar infarction (non internal carotid territory) patient with history of psychosis concomitant lesion e.g Brain tumor concomitant cerebrovascular lesion e.g aneurysm patient without follow up patient with history of neurological disorder that cause neurological deficit multiple cerebrovascular accident or multiple hemorrhagic lesion history of previous cerebrovascular accident bilateral cerebrovascular accident or bilateral hemorrhage concomitant subdural hematoma and intracranial hemorrhage traumatic posterior fossa hematoma intraventricular hemorrhage patient with subdural hematoma and glascow coma scale 3 without brain palsation depressed fracture and patient with dis-usable bone flap patient who underwent temporal lobectomy traumatic injury to thoracic, abdomen, pelvic and their content that need intervention
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **28**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
patient who indicate cerebral decompression (as mentioned before) with sealed envelop method and announce the surgeon who is blind at the end of surgery the method of surgery termination(Hinge cranioplasty or decompressive craniectomy). patient post operation underwent ICU care under supervision of director of study and nursing who are blind of type of surgery.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Imam Khomeini St Hasan abad Sq SINA hospital
City
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Province
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Postal code
1136746911
Approval date
2018-01-15, 1396/10/25
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1396.4230

Health conditions studied

1

Description of health condition studied
patient with malignant intracranial hypertention
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
short term and long term evaluation of effect of hinge cranioplasty in decreasing intracranial pressure

Timepoint
5 day - 3 month - 6 month - 1year
Method of measurement
ICP monitoring with subdural catheter in first 5 day - evaluating the patient with Modified Rankin scale and Glasgow Outcome scale in 3 and 6 month and 1year

Secondary outcomes

1

Description
long term quality of life and complication
Timepoint
3 month - 6 month -1 year
Method of measurement
Modified Rankin scale and Glasgow Outcome scale

Intervention groups

1

Description
Intervention group: patient who had malignant intracranial hypertention and not releived with medical managment randomely devided to two group . On hinge cranioplasty patient underwent question mark incision and after dissection of skin flap the pericraniom will dissected and used for duraplasty after the removal of the frontotemporoparietal bone flap. After duraplasty bone flap will attach loosely with one miniplate to frontal bone and the temporal and parietal miniplate just attached to the bone flap.
Category
N/A

2

Description
Control group: On decompressive craniectomy patient underwent question mark incision and after dissection of skin flap the pericraniom will dissected and used for duraplasty after the removal of the frontotemporoparietal bone flap and it will be inserted on the upper quadrant of the abdomen on the same side of craniectomy. patient underwent cranioplasty after 6 months.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Mohammad Mostafa Harifi
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Mostafa Harifi
Position
Resident of neurosurgery

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
all data can be published after disguised the patient
When the data will become available and for how long
2 Month after publishing the result
To whom data/document is available
data is available for researcher , physician , therapeutic and educational and scientific center
Under which criteria data/document could be used
for increasing treatment efficacy
From where data/document is obtainable
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What processes are involved for a request to access data/document
contacing with authors
Comments